

REMARKS/ARGUMENTS

In response to the Final Office Action mailed June 20, 2006, Applicants propose to amend their application and request reconsideration in view of the proposed amendments and the following remarks. In this amendment, Claim 1 is proposed to be amended, no claims have been added, and no claims have been cancelled so that Claims 1- 40 are currently pending. No new matter has been introduced.

Claims 1-10, 20, 21 and 28-31 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,472,702 to Muth et al (Muth) in view of U.S. Patent No. 5,749,203 to McGowan, Jr. (McGowan) and further in view of EP 0 568 310 to Mitchell (Mitchell) as evidenced by Sigma-Aldrich. Claims 22-27 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Muth in view of McGowan and Mitchell as evidenced by Sigma Aldrich and further in view of U.S. Patent No. 5, 464,580 to Popescu et al. (Popescu). Claims 11-13 and 32-24 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Muth in view of McGowan and Mitchell as evidenced by Sigma Aldrich and further in view of U.S. Patent No. 6, 025, 414 to Rich (Rich) and U.S. Patent No. 3, 675, 647 to Pharriss et al. (Pharriss). Claims 14-19 and 35-40 were rejected under 35 U.S. C. § 103(a) as being unpatentable over Muth in view of McGowan and Mitchell as evidenced by Sigma Aldrich and further in view of WO 00/38754 to Gingras (Gingras). These rejections are respectfully traversed.

The MPEP, in section 706.02(j), sets forth the basic criteria that must be met in order to establish a *prima facie* case of obviousness:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The

teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In *re* Vaeck, 947 F.2d,488,20 USPQ2d 1438 (Fed.Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.

Section 2143.03 of the MPEP clarifies certain criteria in section 706.02(j).

“To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In *re* Royka, 490F.2d 981, 180 USPQ 580 (CCPA 1074). “All words in a claim must be considered in judging the patentability of that claim against the prior art.” In *re* Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In *re* Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).”

Both Muth and McGowan are directed to methods of sterilization. In Muth a device and a protein are being sterilized whereas in McGowan a device is sterilized. More specifically, McGowan teaches the use of ethylene-oxide and steam to sterilize at temperatures in the following ranges: 70° F to 160°F, 90°F to 150°F and more preferably, 120°F to 140°F. As stated in McGowan, this is high temperate sterilization and not for anything else. In the claimed invention, we need low temperature sterilization, 25°C (77°F) to 35 C (95°F). As stated in 2144.05 of the MPEP, *prima facie* obviousness can be overcome, by illustrating the **critically** of the range. In the claimed invention, the range is critical because of the drug.

In addition, since McGowan teaches away from Muth, Applicant requires a more specific showing of why all of the references should be combined. One cannot simply pick and choose from patents using the claimed invention as a template. In Ruiz v. AB Chance Company, 57 USPQ2d, 1161, 1167 (200), the court stated “Because there is a general rule that combination claims can consist of combinations of old elements as well as new elements,” Clearstream Wastewater Sys. v. Hydro-Action, Inc., 206 F.3d 1440, 1446, 54 USPQ2d 1185, 1189-90 (Fed. Cir. 2000), “[t]he notion...that combination claims can be declared invalid merely upon finding similar elements in separate prior patents would necessarily destroy virtually all patents and cannot be the law under the statute, § 103.” Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1575, 1 USPQ2d 1593, 1603 (Fed. Cir. 1987); Arkie Lures, Inc. v. Gene Larew

Tackle, Inc., 119 F.3d 953 957, 43 USPQ2d 1294, 1297 (Fed. Cir. 1997) ("It is insufficient to establish obviousness that the separate elements of the invention existed in the prior art, absent some teaching or suggestion, in the prior art, to combine the elements."). The test is not whether one device can be an appropriate substitute for another.

Since there is no motivation to combine all of the reference, there can be no obviousness rejection. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Applicant would be grateful for the opportunity to conduct a telephonic or in-person interview if the Examiner believes it would be helpful in disposing of the present case.

The Reply raises no new issues and places the application in form for allowance therefore; entry is proper and earnestly solicited.

Respectfully submitted,

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Dated: August 21, 2006